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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/438,185 11/11/99 STEPHENS

R 018941-00041

020350 HM12/0227
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EXAMINER

DUFFY, P

ART UNIT

PAPER NUMBER

1645

7

DATE MAILED:

02/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/438,185

Applicant(s)

Stephens et al

Examiner

Duffy

Group Art Unit

1645

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-10 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-10 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Restriction/Election

1. Prior to setting forth the restriction requirement, it is pointed out that the claims recite improper Markush Groups. M.P.E.P. 803.02 states that: Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unity of invention* [emphasis added], *In re Hamish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." In the instant case, the method and products rely upon polypeptides, polynucleotides and antibodies which differ in both structure and modes of action (function) to such an extent and require non-coextensive searches to such an extent that they are considered to lack a substantial structural feature disclosed as being essential to the disclosed utility.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-8, are drawn to drawn to multiply distinct polynucleotides encoding multiply distinct polypeptides with open reading frames from *C. pneumoniae* as set forth in Table 3, expression cassettes, and methods requiring the use of nucleotides or nucleotide constructs classified in class 536, subclasses 23.1, 23.5, and 24.3, class 435, subclasses 6, 69.1, 320.1, 240.1, and 252.33.

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Groups II. Claim 9, is drawn to multiply distinct polypeptide open reading frames from *C. pneumoniae* as set forth in Table 3, classified in class 530, subclass 350 and class 435, subclass 7.1.

Group IV. Claim 10, is drawn to multiply distinct monoclonal antibodies specific for any open reading frame from *C. pneumoniae* as set forth in Table 3, classified in class 530, subclass 387.1 and 388.1.

3. The inventions are distinct, each from the other for the following reasons.

Group I is independent and distinct from each of Groups II-III because the DNAs, vectors, and host cells and methods are materially different from and are therefore independent and distinct from the polypeptides of Group II and are also materially different from the antibodies of Groups III. Additionally, the DNAs, vectors, and host cells of Group I are not needed to produce the polypeptides of Group II, because the polypeptides of Group II may be purified from naturally occurring sources or may be synthesized chemically. Neither is any of the polypeptides claimed in Groups II needed to produce any of the DNAs, vectors, and host cells of Group I. The DNA, vectors, host cells, and methods of Group I are not necessary for the production of any of the antibodies of Group III, nor are the antibodies needed to make any of the DNAs, vectors, and host cells of Group I or to practice any of the methods of Group I. The polypeptides of Group II are distinct from the antibodies of Group III because they are functionally and chemically distinct. The proteins perform a cellular function whereas the antibodies mediate immune responses and bind the proteins. Each of the polynucleotides encoding polypeptides, polypeptides and antibodies of Groups I-III are distinct, each from the other, because they are chemically and functionally distinct entities and lack a substantial structural feature in common disclosed as being essential to the disclosed utility. Each of the antibodies of Group III are distinct each from

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the other because they are chemically and functionally distinct entities which bind separate distinct polypeptide sequences and the search for an antibody which binds one specific sequence would not encompass the others. The search for one would not encompass a search for any other particular nucleotide or polypeptide sequence.

4. Groups I, II and III, are drawn to multiple individual chemically and functionally distinct polynucleotides, polypeptides and antibodies as set forth above. Should applicant elect Group I Group II or Group III applicant should elect a *single* open reading frame, a *single* polypeptide or *single* monoclonal antibody which binds a single polypeptide for prosecution on the merits will be restricted.

5. Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, and in the absence of restriction would place an undue search and examination burden on the examiner, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and the inventions of the Groups I-III require non-coextensive literature searches, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under

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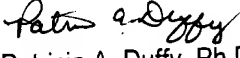
37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

8. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1604 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 6:30 AM to 3:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
February 25, 2001


Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600